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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

NORTHERN MONTANA CARE CENTER, Plaintiff, vs. MICHAEL O. LEAVITT, Secretary of the U.S. Department of Health and Human Services; and MARK B. McCLELLAN, Administrator, Centers for Medicare and Medicaid Services, Defendants.	CV 04-97-GH-SEH FINDINGS AND RECOMMENDATIONS and ORDER

I. FACTUAL BACKGROUND

Plaintiff Northern Montana Care Center ("NMCC") operates a hospital-based nursing facility in Havre, Montana. As part of NMCC's Medicare/Medicaid eligibility requirements, the Montana Department of Public Health and Human Services ("MDPHHS") (on behalf of the Centers for Medicare and Medicaid Services ("CMS"))¹ conducts surveys of NMCC once every

¹The predecessor of CMS was the Health Care Financing Administration ("HFCA"). The HFCA was renamed CMS in July 2001. All references to the agency in this opinion will use the

fifteen months. From April 27 - 30, 1998, such survey of NMCC was conducted.

On May 1, 1998, MDPHHS sent NMCC a Statement of Deficiencies ("SOD"). The SOD informed NMCC that, as a result of the survey, MDPHHS determined that NMCC was non-compliant with 22 of CMS's participation requirements, the most pertinent requirements being: Tags-F 221, F-272, F-279 and F-323.² The Tag-F 221 deficiency was classified as an "immediate jeopardy" situation and was considered the most serious. The SOD indicated that, in light of these deficiencies:

1. MDPHHS recommended to CMS that NMCC's participation in Medicaid/Medicare programs be terminated within 23 days if the immediate jeopardy deficiency (F-Tag 221) was not removed;
2. MDPHHS recommended to CMS that NMCC be denied payment of new admissions ("DPNA") effective immediately;
3. MDPHHS would impose immediate state monitoring;
4. MDPHHS would impose a "Directed Plan of Correction" within 10 days if NMCC would not submit an acceptable Plan of Correction ("PoC") for the Tag-F 221 deficiency; and
6. NMCC was to submit an acceptable PoC for all other deficiencies within 10 days after receiving notice of the deficiencies. *A.R. 115-117.*

On May 6, 1998, MDPHHS surveyors returned to NMCC and determined that all Tag-F 221 deficiencies had been corrected. On May 7, 1998, MDPHHS sent NMCC a letter informing them that, in light of the Tag-F 221 deficiency, MDPHHS "MUST withdraw" approval of NMCC's nurse aide training and competency evaluation program ("NATCEP"). MDPHHS

current name.

²Tag-F 221 relates to the use of bedrails as restraints. Tag-F 272 relates to the performance of periodic comprehensive assessments of a resident's needs. Tag-F 279 relates to the development of a comprehensive care plan for each resident that includes objectives and timetables reflecting a resident's medical, mental and social needs. Tag-F 323 relates to the requirement that a facility maintain an environment that is as free of accident hazards as is possible.

stated that they found the Tag-F 221 citation to reflect a “substandard quality of care.” On May 11, 1998, MDPHHS also sent letters to the Montana Board of Nursing Home Administrators and the attending physician of each NMCC resident informing them that NMCC had been cited for “substandard quality of care” because of the Tag-F 221 deficiency.

On May 12, 1998, MDPHHS sent a letter advising NMCC as follows: (1) the Tag F-221 deficiency had been corrected and NMCC’s “immediate jeopardy” status had been removed as of May 6, 1998; (2) NMCC’s “fast track termination” from the Medicare/Medicaid program would be lifted; (3) NMCC would have until October 30, 1998, to correct all other deficiencies or MDPHHS would recommend to CMS that NMCC’s participation in the Medicare/Medicaid program be terminated. *A.R. 131*. That same letter informed NMCC that although the Tag-F 221 deficiency had been corrected, there were other isolated deficiencies that required significant corrections. *Id.*

On May 14, 1998, CMS sent a letter to NMCC notifying them that:

1. In light of the May 6 re-survey and NMCC’s subsequent compliance with Tag-F 221, NMCC’s “immediate jeopardy” status had been removed and Medicare/Medicaid termination would not be imposed;
2. NMCC was still not in compliance with 22 other Medicare/Medicaid participation requirements;
3. MDPHHS’ recommendations of state monitoring and a Directed PoC if an acceptable PoC was not received were appropriate;
4. As a consequence of the 22 non-compliance requirements, CMS would impose the remedy of DPNA effective May 29, 1998;
5. Where there has been a Denial of Payment, CMS is required to withdraw approval of NATCEP for a period of 2 years; and
6. CMS’ decision was appealable to an ALJ.

A.R. 237-239.

On May 20, 1998, NMCC informed MDPHHS that they disputed the 22 alleged

deficiencies and wished to proceed through the Informal Dispute Resolution (“IDR”) process.

On June 8, 1998, after the IDR meeting, MDPHHS notified NMCC that it would modify the SOD as follows:

1. Nine (9) of the 22 Tag-F deficiencies would be deleted based on the information received at the IDR;
 2. Thirteen of the cited Tag-F deficiencies would be modified or reduced;
 3. The corrected “immediate jeopardy” deficiency (Tag-F 221) would not be deleted but would be reduced in severity;
 4. The DPNA penalty and the withdrawal of NATCEP approval would remain in place; and
 5. If substantial compliance was not achieved by October 30, 1998, NMCC’s participation agreement with Medicare/Medicaid would be terminated.
- A.R. 248-253.*

On June 24, 1998, MDPHHS surveyors conducted a follow-up survey of NMCC and found NMCC to be in substantial compliance with all participation requirements. As a result, MDPHHS withdrew the DPNA effective June 29, 1998. *A.R. 430.* During the DPNA period, NMCC took in one Medicaid and nine Medicare admissions. NMCC was unable to collect \$43,600 in Medicare/Medicaid revenue from May 29 through June 22, 1998, the 25 day period the DPNA was in effect.

II. PROCEDURAL STATUS

NMCC’s Amended Complaint alleges the following 10 causes of action against

Defendants:

- I. Defendants violated the Social Security Act and the APA when they implemented constantly changing survey protocols, procedures and guidelines without meeting the public notice and public comment requirements;
- II. Defendants violated the Medicare and Medicaid Acts, the APA, and the Fifth Amendment when they took adverse action against NMCC using survey protocols, procedures and guidelines that were not regulations

and/or were in conflict with their enacting statutes. Additionally, Defendants unlawfully relied on unqualified individuals to conduct surveys, make decisions and offer testimony concerning the medical care of NMCC patients;

- III. Defendants violated the Medicare and Medicaid Acts and the APA when they adopted a Tag-F 221 regulation (the use of bed rails as restraints) that is more restrictive than the implementing statutory language.
- IV. Defendants violated the Medicare and Medicaid Acts and the APA when they cited Plaintiff with a violation of Tag-F 221 and precluded Plaintiff from presenting argument on that violation at the administrative hearing;
- V. Defendants violated the APA and Fifth Amendment when they revoked NMCC's NATCEP program based on the immediate jeopardy determination under Tag-F 221;
- VI. Defendants violated the APA when they illegally shifted the burden of proof to NMCC to prove by a preponderance of the evidence that it was in compliance with Medicare/Medicaid program requirements;
- VII. Defendants violated the Fifth Amendment when they publicly reported and published deficiencies that were either rescinded by CMS and/or undecided by the ALJ causing the deprivation of NMCC's property and reputational interests;
- VIII. Defendants violated the Eighth Amendment when they imposed the excessive DPNA penalty;
- IX. Defendants violated the APA when they relied on the use of trainees as surveyors in citing deficiencies contrary to the authorization of the implementing statute; and
- X. Defendants violated the Medicare and Medicaid Acts and the APA when the ALJ and Departmental Appeals Board ("DAB") found Plaintiff to have been in violation of Tag-F deficiencies 272, 279 and 323.

Presently before the Court are the parties' cross-motions for summary judgment.

NMCC's Summary Judgment Motion claims:

- 1. The factual and legal issues decided by the DAB in its Final Decision of

July 12, 2004, should be reversed and/or substantially modified;

2. NMCC was denied an opportunity to make a factual record during the administrative proceedings on the Tag-F 221 deficiency and that the Tag-F 221 regulation is contrary to its implementing statute and therefore illegal;
3. The imposition of the DPNA remedy was impermissibly severe;
4. Plaintiff had a right to have all thirteen cited deficiencies to be resolved and ruled upon by the ALJ;
5. The 1998 Survey of NMCC was unlawful because it relied on survey materials that were not subject to public notice and comment; and
6. The 1998 Survey of NMCC was unlawful because it used trainees as surveyors.

In response, Defendants contend that the agency's Final Decision was neither arbitrary or capricious, nor an abuse of discretion.

NMCC, in its reply brief, concedes that because it failed to present the following three legal issues to the ALJ, it has failed to preserve its right to judicial review:

1. NMCC's assertion that its constitutional and statutory rights were violated by Defendants' continuing public disclosure of all 14 deficiency citations remaining after IDR, including the 10 deficiencies not heard, decided or reversed by the DAB;
2. NMCC's assertion that its constitutional rights were violated by Defendants' regulation prohibiting NMCC from appealing disapproval of its NATCEP based on the Tag F-221 deficiency citation; and
3. NMCC's assertion that Defendant's unlawfully shifted the burden of proof to NMCC in the administrative hearing.³

As such, this Court will recommend that Defendants' Motion for Summary Judgment on these claims be GRANTED without further discussion.

³NMCC's Reply Brief, p. 15.

Also before the Court is the NMCC's Motion to Supplement the Record with the affidavits of Lori Henderson and Rose Hughes. Generally, a district court's review of an ALJ decision is limited to the certified administrative record. *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Defendants argue that these affidavits are outside of the administrative record and that NMCC has failed to show good cause for their admission.

In support of supplementation, NMCC argues that these affidavits contain at least four letters relating to the deficiencies and remedies at issue that were not in the administrative record submitted by Defendants. However, this Court notes that only the Affidavit of Lori Henderson contains the missing letters noted.

A review of the affidavits reveals that they contain statements and exhibits that are well beyond the scope of the four missing documents. The Court will GRANT the motion with respect to the four missing documents. All other aspects of the Affidavits will not be considered. Accordingly, NMCC's Motion to Supplement the Record is GRANTED IN PART and DENIED IN PART.

III. STANDARD OF REVIEW

A. Summary Judgment

The Federal Rules of Civil Procedure provide for summary adjudication when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ.P. 56(c)*.

In considering a motion for summary judgment, the court must examine all of the evidence in the light most favorable to the non-moving party. *United States v. Diebold, Inc.*, 369

U.S. 654, 655 (1962). If the moving party does not bear the burden of proof at trial, he or she may discharge this burden of showing that no genuine issue of material fact remains by demonstrating that "there is an absence of evidence to support the non-moving party's case." *Celotex Corporation v. Catrett*, 477 U.S. 317, 325 (1986). Once the moving party meets the requirements of Rule 56 by showing there is an absence of evidence to support the non-moving party's case, the burden shifts to the party resisting the motion, who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

B. Administrative Procedure Act

The Administrative Procedure Act ("APA") provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. The APA limits the scope of judicial review of agency actions. Generally, a court may not set aside an agency action unless that action was "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A); *Maximum Comfort, Inc. v. Thompson*, 323 F.Supp.2d 1060, 1065 (E.D.Cal. 2004); *Citizens to Preserve Overton Park v. Volpe*, 410 U.S. 402, 416 (1971). "To make this finding, the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Volpe*, 401 U.S. at 416. "Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency." *Id.*

In determining whether an agency's actions were arbitrary, capricious, an abuse of

discretion, or otherwise not in accordance with the law, "the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706. "The focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985). "The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court." *Id.* at 743-44. A court may not consider information "that was not available at the time the [agency] made its decision." *Airport Communities Coalition v. Graves*, 280 F.Supp.2d 1207, 1213 (W.D.Wash. 2003).

The Court's function is not to assess which of several competing interpretations best serves the regulatory purpose. *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994). Nor is the Court permitted to substitute its judgment for that of the agency. *Marymount Hosp., Inc. v. Shalala*, 19 F.3d 658, 661 (C.A.D.C. 1994). Moreover, a reviewing court must defer to an agency's interpretation unless an "alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." *Thomas Jefferson*, 512 U.S. at 512 (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430 (1988)).

Broad deference is particularly warranted when "the regulation concerns 'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Id.* (quoting *Pauley v. BethEnergy Mine, Inc.*, 501 U.S. 680, 697 (1991)); see also *Marymount Hosp.*, 19 F.3d at 661.

IV. DISCUSSION

A. Deficiency Findings

On July 13, 1998, NMCC sought an administrative hearing on the allegations of non-compliance that resulted in the imposition of the DPNA. Prior to the hearing, CMS filed a motion seeking to strike the Tag-F 221 deficiency and all issues relating to it from the hearing on the grounds that CMS did not rely on that deficiency in imposing the DPNA remedy. In a pre-hearing order, the ALJ issued a ruling striking all Tag-F 221 issues from the hearing except to the extent those issues related to Tag-F 272.⁴ *A.R.* 582-585, 695. In reaching this conclusion, the ALJ found that by letter dated May 14, 1998, CMS had informed NMCC that it had found NMCC to have corrected the F-221 deficiency by May 6, 1998, and that it would impose the DPNA penalty effective May 29, 1998, based on the other deficiencies noted in the SOD.

An administrative hearing was held from September 9 - 12, 2002. The hearing involved the remaining thirteen alleged deficiencies. NMCC was given an opportunity to present evidence on all thirteen deficiencies. On June 25, 2003, the ALJ issued a decision. The ALJ concluded that the sole issue before him was whether NMCC was out of substantial compliance with at least one Medicare participation requirement. *A.R.* 4. The ALJ thus chose to discuss only four of the thirteen deficiencies. In reaching this decision, the ALJ concluded that it was not necessary for him to make findings on each deficiency or on every resident since CMS is authorized to impose a DPNA if a provider is found to be out of substantial compliance with even a single participation requirement. 42 C.F.R. §§ 488.408(d)(3), 488.417.

⁴As stated earlier, Tag-F 272 relates to the performance of periodic comprehensive assessments of a resident's needs.

The ALJ found NMCC to be in substantial non-compliance with four participation requirements, specifically, Tag-F 272, 279, 323 and 333.⁵ In reaching this conclusion, the ALJ thoroughly discussed each of these requirements. After referencing each requirement, the ALJ discussed what evidence he relied on to support the finding of each deficiency and reviewed Plaintiff's responses to this evidence. *A.R. 6 - 18*. Further, in discussing each of the four F-Tags, the ALJ cited to the SOD and used specific residents as detailed examples to support his findings. *Id.* Since the ALJ found NMCC to not be in substantial compliance, he further concluded that CMS had a basis for imposing the DPNA. *Id.*

NMCC then appealed the ALJ's ruling to the DAB. Specifically, NMCC appealed: (1) the ALJ's decision sustaining four of CMS' deficiency findings; and (2) a May 15, 2001, Order striking certain claims of NMCC, primarily issues surrounding the F-221 deficiency. After review, the DAB sustained the ALJ's rulings that NMCC was not in substantial compliance with three of the four of the Medicare/Medicaid participation requirements, specifically, Tag-F 272, 279, 323. *A.R. 30-52*. The DAB modified the ALJ's finding as to Tag-F 333. *A.R. 50-56*. The DAB sustained the ALJ's conclusion regarding the DPNA. Further, the DAB sustained the ALJ's order striking hearing on the issues relating to the Tag-F 221 deficiency involving the "immediate jeopardy" on the grounds that CMS did not rely on that deficiency in imposing the DPNA remedy. *A.R. 23-28*.

⁵Certified MDPHHS surveyors provided testimony at the administrative hearing that they observed and documented at least three of these deficiencies. Surveyor Linda Chapman testified that she observed and documented three violations of Tag-F 279 in regards to Patients # 4, 5, and 16. *A.R. 684 - 686*. Surveyor LaDawn Whiteside-Hendricks testified that she observed and documented two violations of Tag-F 323. *A.R. 398 - 400*. Surveyor Janet Collins testified that she observed and documented three violations of Tag-F 272 in regards to Patients # 2, 9 and 19. *A.R. 139 - 149*.

This Court notes that NMCC's briefs before this Court do not challenge the DAB's decision to sustain the ALJ's findings of deficiencies as to Tags-F 272, 279 and 323. NMCC also does not dispute that 42 C.F.R. § 488.402 allows for the imposition of "one or more remedies for each deficiency constituting non-compliance or for all deficiencies constituting noncompliance." *Id.* Moreover, the regulations allow Defendants to impose a DPNA penalty when there "are [w]idespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy" or "[o]ne or more deficiencies that constitute actual harm that is not immediate jeopardy." 42 C.F.R. § 488.408(d)(2)(i)&(ii). *A.R. 21.* Further, does not dispute that 42 C.F.R. §§ 488.408(d)(3)(I), 488.417 allows for the DPNA remedy when a facility is found to be non-compliant with its participation requirements. *See also 42 U.S.C.A. § 1395i-3(h)(2)(B).*⁶

As such, this Court concludes that the ALJ's finding that CMS was authorized to impose the DPNA remedy because NMCC was not in substantial compliance with at least three of its participation requirements was not "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). Defendant's Motion for Summary Judgment on this ground should be GRANTED.

B. Tag-F 221

NMCC makes two arguments regarding the F-221 deficiency. First, it argues that the ALJ erred when he granted the CMS' motion to strike any discussion of the Tag-F 221

⁶This Opinion will reference code sections from both the Medicare and Medicaid Acts.

deficiency citation from the hearing.⁷ Second, NMCC argues that the Tag-F 221 substantive rule is illegal and invalid because it is impermissibly narrow and contradicts the enacting statutes from which the rule was derived. In granting the CMS' motion to strike, the ALJ concluded that Defendants did not rely on this deficiency in the imposition of penalties. For this Court to reach NMCC's second argument regarding the legality of the Tag-F 221 rule, this Court must first find that the ALJ's decision to strike discussion of the Tag-F 221 deficiency citation from the hearing to be arbitrary and capricious.

NMCC alleges that the ALJ erred when he granted the Defendants' motion to strike discussion of the F-221 deficiency from the hearing. It contends that the F-221 deficiency was the real basis for the imposition of the DPNA and therefore, it should have had an "opportunity to make a factual record or legal arguments regarding the Tag-F 221 citation."⁸

In granting CMS' motion to strike the F-221 deficiency, the ALJ relied on CMS' letter of May 14, 1998, reflecting that NMCC was back in compliance with its F-221 requirements before the imposition of the DPNA. *A.R.* 583-84. The DAB found that the May 14, 1998, letter was evidence that CMS did not initially intend to base the DPNA on the F-221 deficiency. *A.R.* 25. In affirming the ALJ's decision to strike the F-221 deficiency from the hearing, the DAB stated that the regulations allowed Defendants to impose a DPNA penalty when there "are [w]idespread

⁷Tag-F 221 relates to the use of bed rails as restraints. The F-221 deficiency was considered an "immediate jeopardy" situation. An "immediate jeopardy" category is the most serious deficiency that can be cited and means that a facility's non-compliance "has caused, or is likely to cause, serious injury, harm, impairment or death to a resident." 42 C.F.R. § 488.301.

The ALJ did amend that ruling to allow Plaintiff limited discussion of the Tag-F 221 deficiency to the extent that it related to the Tag-F 272. *A.R.* 695.

⁸ *NMCC's Brief In Support of Summary Judgment*, p. 13.

deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy” or “[o]ne or more deficiencies that constitute actual harm that is not immediate jeopardy.” 42 C.F.R. § 488.408(d)(2)(i)&(ii). *A.R.* 21. Further, the DAB found that CMS’ regulations allowed issues for hearing to be modified to account for subsequent actions. 42 C.F.R. §§ 498.30, 498.49(b), 498.56. Given that CMS could withdraw its reliance on a particular deficiency (in this case, the F-221) as a basis for a remedy, the DAB found that there was “no reason why CMS should not be able to clarify that it did not intend in the first instance to base a remedy on a particular deficiency.” *A.R.* 25-26. The DAB further concluded that NMCC’s speculation that the “state survey agency would not have recommended any remedies in the absence of the immediate jeopardy-level deficiency does not provide a basis to overturn the remedy that CMS selected.” *A.R.* 26.

In reviewing the record, the Court notes that a letter was sent from MDPHHS to NMCC on May 1, 1998, the day after the NMCC’s survey was completed. That letter informed NMCC that its facility was not in substantial compliance with its Medicare/Medicaid requirements. This non-compliance included an “immediate jeopardy” situation in light of the Tag-F 221 deficiency. As such, MDPHHS recommended to CMS that: (1) NMCC’s Medicare/Medicaid participation agreement be terminated effective May 23, 1998; (2) NMCC be denied payment for new admissions effective immediately; and (3) NMCC undergo state monitoring effective immediately. *A.R.* 116. That same letter informed NMCC that a change in the seriousness of the non-compliance to “non-immediate jeopardy” may result in a change in the remedy selected. *Id.* The letter also ordered NMCC to submit a plan of correction (“PoC”) for the Tag-F 221 deficiency.

On May 6, 1998, MDPHHS surveyors returned to NMCC and found all Tag-F 221 deficiencies to have been corrected and that NMCC was again in substantial compliance with respect to that F-Tag. On May 12, 1998, MDPHHS sent a letter advising NMCC that the Tag F-221 deficiency had been corrected and NMCC's "immediate jeopardy" status had been removed as of May 6, 1998, and that NMCC would have until October 30, 1998, to correct all other deficiencies or MDPHHS would recommend to CMS that NMCC's participation in the Medicare/Medicaid program be terminated. *A.R. 131*. That letter went on to state: "[H]owever, the additional deficiencies cited at the 4-30-98 survey were found to be isolated deficiencies that constitute actual harm that is not immediate jeopardy . . . whereby significant corrections are required . . . Your facility must provide a plan of correction (PoC) to this office for these deficiencies." *Id.* Lastly, in light of the additional deficiencies, MDPHHS recommended that all remedies, save fast-track termination, remain the same. *A.R. 132*.

As set forth earlier in this opinion, the May 14, 1998, letter sent by CMS to NMCC notified them that:

1. In light of the May 6 re-survey and NMCC's subsequent compliance with Tag-F 221, NMCC's "immediate jeopardy" status had been removed and Medicare/Medicaid termination would not be imposed ;
2. NMCC was still not in compliance with 22 other Medicare/Medicaid participation requirements;
3. MDPHHS' recommendations of state monitoring and a Directed PoC if an acceptable PoC was not received were appropriate;
4. As a consequence of the 22 non-compliance requirements, CMS would impose the remedy of DPNA effective May 29, 1998;
5. Where there has been a Denial of Payment, CMS is required to withdraw approval of NATCEP for a period of 2 years. *A.R. 237-239*.

From a review of these letters to NMCC, it is clear to this Court that CMS considered the Tag-F 221 deficiency to have been corrected as of May 7, 1998. Further, the May 12, 1998, letter

evidences that although Defendants considered the Tag-F 221 deficiency to have been corrected, NMCC still had a number of “additional deficiencies” that required “significant corrections.”

A.R. 131. The May 14, 1998, letter reiterated the fact that the F-221 deficiency had been corrected and that termination from the Medicare/Medicaid participation agreement would not occur because of that deficiency. That letter further reflected that NMCC was still not in compliance with 22 other participation requirements and as a consequence, CMS would impose the DPNA remedy.

Other than raising the allegation that the ALJ erred in striking discussion of the F-221 deficiency from the hearing, the entirety of NMCC’s discussion in its brief does not appear to mention the facts surrounding the imposition of the deficiency. Rather, NMCC’s argument focuses on its concerns that Defendants’ attempts to avoid the APA’s requirements of public notice and comment in developing a bed rail restraint rule that is both impermissibly narrow and vague. Given that NMCC is before this Court seeking judicial review of the ALJ’s final decision, NMCC must show that the ALJ arbitrarily and capriciously failed to address the F-221 deficiency before it can take issue regarding the legality of the F-221 regulations themselves.

From the facts of this case, this Court must conclude that the ALJ’s decision granting CMS’ motion to strike discussion of the F-221 deficiency was not arbitrary and capricious, nor was it an abuse of discretion, or otherwise not in accordance with the law. Defendants’ Motion for Summary Judgment on this ground should be GRANTED.

C. The Severity of the DPNA Remedy

NMCC claims that Defendants denied it the opportunity to challenge the basis for or reasonableness of the DPNA remedy. Again, NMCC raises the argument that the F-221 citation

was the basis for the DPNA penalty and that NMCC was not afforded an opportunity for a hearing. As this Court has already denied NMCC's F-221 claim, no further discussion of this issue is necessary.

As to the imposition of the DPNA penalty, this Court has already noted that Defendants may impose the DPNA upon a finding of any one deficiency. NMCC had an opportunity at the administrative hearing to make legal and factual arguments in opposition to Defendants' deficiency allegations. The Court again notes that NMCC does not object to the ALJ's findings of at least three deficiencies. Consequently, Defendant was authorized by regulation and statute, upon a finding of a deficiency, to impose the DPNA remedy. As to whether the DPNA remedy was too severe a penalty in comparison of the deficiencies found, this Court is not permitted to substitute its judgment for that of the Agency. *Marymount Hosp.*, 19 F.3d at 661. Here, because Defendants had a factual and regulatory basis for their imposition of the DPNA remedy, this Court cannot conclude that Defendants' decision regarding the choice of penalty was arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law. Defendants' Motion for Summary Judgment on this ground should be GRANTED.

D. Review of Each Deficiency

Citing judicial economy and the fact that CMS only had to prove one deficiency in imposing a penalty, the ALJ reviewed only 4 of the 13 deficiencies in upholding CMS' imposition of the DPNA. NMCC alleges that its due process rights were denied when the ALJ declined to address all 13 deficiency identified in the SOD. In response, Defendants cite to the DAB case of *Beechwood Sanitarium v. CMS*, wherein it was concluded that the ALJ decision to discuss only a few of the deficiencies raised at the hearing was an exercise of judicial economy

that was within his discretion. Decision No. 1824 (2002), p. 13, 2002 WL 848030 (HHS). At the administrative hearing, NMCC presented evidence and argument on all deficiencies raised in the SOD.

NMCC contends that under the present regulations, these unresolved deficiencies can be used against it at some future proceeding. Specifically, NMCC cites to 42 C.F.R. § 488.404(c)(2) wherein a “facility’s prior history of non-compliance in general and specifically with reference to the cited deficiencies” can be used as a factor in selecting the type of remedy to be imposed.⁹

Consequently, NMCC contends that its due process rights were violated when Defendants used administrative rulings and regulations to deny NMCC the opportunity to seek review of the Defendants’ SOD decisions. Further, NMCC argues that it has a constitutionally protected property interest in continued participation in the Medicare/Medicaid programs. In support of its property interest claim, NMCC relies on *Vencor Nursing Centers, L.P. v. Shalala*, 63 F.Supp.2d 1, 10 (D.D.C. 1999) and *Estate of Smith v. Bowen*, 675 F.Supp. 586, 589 (D.Co. 1987). Although these cases are on point, they are district court cases that are from other circuits. The law for this circuit, however, is to the contrary.

A due process claim is cognizable only if there is a recognized liberty or property interest at stake. *Board of Regents v. Roth*, 408 U.S. 564, 569 (1972); *Schroeder v. McDonald*, 55 F.3d 454, 462 (9th Cir. 1995).¹⁰ In *Erickson v. DHHS*, 67 F.3d 858, 862 (9th Cir. 1995), the Ninth

⁹See also 42 C.F.R. § 488.438((f)(1).

¹⁰In its summary judgment brief, NMCC alleges, without discussion, that Defendants deprived it of its “reputational liberty interest without due process of law.” *Plf. Sum. Jud. Br. at* 35. A person’s liberty interest is implicated if (1) a charge impairs his reputation for honesty or

Circuit noted that to have a property interest in a benefit, “a person must have ‘a legitimate claim of entitlement to it.’” *Id.* at 862 (citing *Roth*, 408 U.S. at 577). These “entitlements are created by ‘rules or understandings’ from independent sources, such as statutes, regulations, and ordinances, or express or implied contracts.” *Orloff v. Cleland*, 709 F.2d 372, 377 (9th Cir. 1983) (citing *Roth*, 408 U.S. at 577). The *Erickson* Court went on to discuss the Tenth Circuit Court case of *Koerpel v. Heckler*, 797 F.2d 858, 863-65 (10th Cir. 1986), wherein that Court found that a physician was not the intended beneficiary of the Medicare program and therefore his injury was “not of constitutional significance for the establishment of a protectable property interest.” *Erickson*, 67 F.3d at 862 (citing *Koerpel*, 797 F.2d at 863-865).¹¹ In conclusion, the Court found that the Plaintiffs had offered no argument to show that they were entitled to the continued participation in Medicare/Medicaid programs and therefore had no property interest. Without a recognized property interest in the continued participation in Medicare/Medicaid programs, NMCC cannot claim that the ALJ’s decision not to rule on all of its deficiencies was a violation of due process. Consequently, NMCC has not presented a cognizable claim. Defendants’ Motion for Summary Judgment on this claim should be GRANTED.

morality. *Erickson*, 67 F.3d at 862 (citing *Vanelli v. Reynolds School Dist. No. 7*, 667 F.2d 773, 777 (9th Cir. 1982)). The record does not reflect that Defendants’ deficiency citations charged NMCC with dishonesty. Nor, in this Court’s opinion, can the deficiency citations be considered charges of moral turpitude. Rather, they are citations alleging substandard care which are closer in character to charges of regarding professionalism. *Rafael Convalescent Hosp. v. Shalala*, 1998 WL 196469, ¶ 5 (N.D.Cal. 1998). Given that a charge of professional incompetence does not impose “a stigma of moral turpitude,” this Court concludes that NMCC’s liberty interests are not at issue. *Id.* (citing *Roley v. Pierce County Fire Protection Dist.*, 869 F.2d 491, 495 (9th Cir. 1989)).

¹¹This case dealt with a physician’s financial loss because of his exclusion from Medicare.

E. Survey Materials

NMCC argues that the survey materials used during the April 30, 1998, survey were illegal because they were based on constantly changing substantive SOM guidelines that were not subject to the public notice and comment provisions of the APA. Specifically, NMCC attacks the legal validity of the Tag-F 221 and Tag-F 329 regulations.

Looking at the issue of public notice and comment in the development of survey materials, this Court is persuaded by the reasoning of the Court in *Vencor Nursing Ctrs., L.P. v. Shalala*, 63 F.Supp.2d 1 (D.D.C. 1999). The *Vencor* Court concluded that survey protocol constituted procedural rules that were not subject to notice and comment rulemaking. In *Vencor*, an owner of a nursing home facility that participated in the Medicare and Medicaid programs contested CMS' actions, including its use of survey forms and procedures, as violative of the notice and comment requirements of APA. *Id.* at 11. The *Vencor* Court rejected this argument, finding that it “was not substantially likely to find that the SOM survey provisions are substantive rules subject to notice-and-comment requirements of the APA and the Medicare Act.” *Id.*

In *Beverly Health & Rehabilitation Services, Inc. v. Thompson*, 223 F.Supp.2d 73, 99 (D.D.C. 2002), the Court agreed with the *Vencor* Court and concluded that the survey protocols were not substantive rules that required notice and public comment but rather “procedural in nature.” That Court held that the survey protocol is “a compliance handbook issued to federal and state officials charged with conducting the surveys in compliance with OBRA ‘87’s requirements.” *Id.* at 101 (citing *Cnty. Nutrition Institute v. Young*, 818 F.2d 943, 949 (D.C.Cir. 1987)). Further, the Court found that this was reflected in the fact that the SOM informed surveyors that they were not to look at the survey protocol in determining “whether observations

merit a deficiency citation, rather surveyors were to “look to the substantive requirements in the statute and regulations to determine whether a citation of non-compliance is appropriate” and base any deficiency on a violation of the statute or regulations.” *Id.* at 102. As such, this Court finds the NMCC’s argument on this claim to be without merit. Defendants’ Motion for Summary Judgment on this ground should be GRANTED.

F. Trainees

NMCC next raises claims that the regulation allowing the use of trainees in an on-site survey is contrary to its enacting statute. In response, Defendants make a number of arguments: (1) the regulation that NMCC is presently challenging does not relieve it of its obligation to demonstrate that it has complied with all its Medicare/Medicaid participation requirements; (2) NMCC never challenged the regulation (42 C.F.R. § 488.314(c)(3)) in the administrative proceedings; and (3) 42 C.F.R. § 488.314(c)(3) was promulgated with public notice and comment.

Defendants contend that, even assuming *arguendo* that the trainee regulation was arbitrary and capricious, inadequate survey performance does not relieve a Nursing Facility of its obligation to meet all requirements for program participation. 42 C.F.R. § 488.318(b). Under Defendants’ theory, regardless of any inadequate survey performance, the ALJ had already concluded and Plaintiff has not disputed that NMCC had not met at least three requirements for program participation and therefore any discussion on this issue is immaterial. As this Court has already affirmed the imposition of the DPNA based on at least one deficiency, this argument is moot. However, there remains an issue as to the use of trainees regarding the remaining nine unresolved deficiencies.

Looking at NMCC’s statutory argument, generally, upon judicial review of an

administrative proceeding, NMCC may not raise claims not adjudicated through the hearing. However, relying on *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), NMCC contends that it may raise constitutional and statutory claims that were not or could not be decided through the administrative appeal.

In *Illinois Council*, an association of nursing homes invoked the district court's federal question jurisdiction and sued the Secretary claiming that certain Medicare health and safety regulations violated various statutes as well as the Constitution. 529 U.S. at 5. In that case, the Court addressed whether a district court had federal question jurisdiction to hear a challenge to certain Medicare regulations. The regulations allegedly violated constitutional and statutory requirements. *Id.* at 7. A provision of the Medicare Act incorporated 42 U.S.C. § 405(h).¹² The *Illinois Council* Court interpreted its prior ruling in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), as holding that § 1331 federal question jurisdiction would exist if without it "application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Id.*; see generally *Fanning v. United States*, 346 F.3d 386, 393-400 (3rd Cir. 2003).

In *Illinois Council*, the Court held that, despite the fact that some claims, such as constitutional or statutory challenges, cannot be resolved administratively, they must still proceed

¹²In 42 U.S.C. § 1395ii, the Medicare Act incorporates 42 U.S.C. § 405(h), which provides that the Secretary's findings and final decision after a hearing are binding on the parties to the hearing. This provision also limits judicial review as follows: "No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided" and no action against the Secretary "shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under" the Medicare Act. 42 U.S.C. § 405(h).

first through the administrative process. *Id.* at 23-24. Such claims are subject to plenary judicial review under the Medicare remedial scheme only after the administrative review process has been exhausted. *Id.* As the Court concluded:

After the action has been so channeled, the court will consider the contention when it later reviews the action. And a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide, including, where necessary, the authority to develop an evidentiary record. *Id.*

In discussing the importance of presentment through the administrative process, the *Illinois Council* Court stated that “proceeding through the agency in this way provides the agency the opportunity to reconsider its policies, interpretations, and regulations in light of those challenges At a minimum, however, the matter must be presented to the agency prior to review in a federal court. This the Council has not done.” *Id.* at 24.

There is evidence that NMCC raised the trainee issue to the DAB pursuant to *Illinois v. Shalala*. However, the DAB declined to allow NMCC to make factual and legal record on the grounds that presentment was all that was necessary to preserve the issues for judicial review. *A.R.* 28. It appears that the DAB misconstrued the *Illinois* case. That case concluded that the Medicare statute “demands the ‘channeling’ of virtually all legal attacks through the [DHHS]” before a health care provider may seek judicial review of a claim arising under the Medicare statute. *Id.* at 13. This “nearly absolute channeling requirement” serves important governmental interests in administrative efficiency and judicial economy, and “assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes.” *Id.* at 2. The “mere presentment” as the DAB suggests clearly does not achieve these governmental interests. This Court concludes that NMCC attempted to raise the issue regarding the use of trainees at the

administrative hearing and therefore this Court will consider NMCC's statutory allegations.

NMCC cites to 42 U.S.C. §§ 1395i-3(g)(2)(E)(iii), which states in relevant part that no "individual shall serve as a member of a survey team unless the individual has successfully completed a training and testing program in survey and certification techniques that has been approved by the Secretary." NMCC contends that the Defendants' adoption of 42 C.F.R. § 488.314(c)(3) is in direct contravention of the aforementioned statute.¹³ Further, NMCC asserts that even if Defendants could justify a trainees' participation in a survey as permissible for purposes of gaining experience, it is still in direct contravention of the statute. NMCC argues that the use and reliance by Defendants on these trainees was illegal and as such, was arbitrary, capricious, an abuse of discretion and therefore all resultant action arising from their participation should be set aside.

At the 1998 survey at issue, of the six surveyors present, three were "trainees." The record amply demonstrates that they were fully involved in the survey of NMCC's facility. For example, when then-trainee Julie Rooney was asked what her role was at the NMCC survey, she testified, "[I] was a nurse surveyor on the survey." *A.R.* 220. Moreover, it appears from the record that MDPPHS did not distinguish the trainees from the certified surveyors. *A.R.* 115. Additionally, the record appear to support the statement in NMCC's reply brief that 44 of the 62 patient-specific deficiency allegations were based on the testimony of the three trainees who allegedly could not, by statute, be survey team members.

¹³42 C.F.R. § 488.314(c)(3) states:

The survey agency may permit an individual who has not completed a training program to participate in a survey as a trainee if accompanied on site by a surveyor who has successfully completed the required training and testing program.

When reviewing regulations, the Court must give considerable weight to a Secretary's judgment that a particular regulation fits within statutory constraints. *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 86 (2002)¹⁴; *United States v. O'Hagan*, 521 U.S. 642, 673 (1997). Deference to the Secretary, however, has important limits. A regulation cannot stand if it is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* To determine whether regulation is a valid exercise of the Secretary's authority, a court must consult the Act, viewing it as a "symmetrical and coherent regulatory scheme." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995).

Here, when the CMS opened 42 C.F.R. § 488.314(c)(3) for public comment, they received numerous comments regarding different aspects of survey training. 59 *Fed. Reg.* 56116 (November 10, 1994). After discussing many of these comments, CMS responded that

We also disagree that surveyors who have not yet completed the training and testing program should "be excluded from active participation." We do not want to prohibit the "historic" role of observers mentioned by two of the commenters, that is, to " * * * collect information to be used by qualified surveyors during the deficiency decision making process," or forbid individuals from making valuable contributions to the survey process if they are in a position to do so. We are, therefore, amending this section (§488.164(d) in the proposed rule) redesignated as §488.314(c)(3) in the final rule, to provide that the survey agency may permit an individual who has not completed a training program to participate in a survey as a trainee if accompanied onsite by a surveyor who has successfully completed the required training and testing program. 59 *Fed. Reg.* 56144.

It is undisputed that § 488.314(c)(3) is broader than its enacting statute. Given the statutory language of 42 U.S.C. § 1395i-3(g)(2)(E)(iii) which states that "no individual shall serve as a member of a survey team unless the individual has successfully completed a training and

¹⁴Although this case deals with the regulations of the Secretary of Labor, this Court finds its holding relevant here.

testing program,” it is evident that Congress’ language is plainly that “of obligation rather than discretion.” *Bennett v. Spear*, 520 U.S. 154, 172 (1997). Defendants’ attempts to rely on its decision to allow public comment on this regulation is unpersuasive. Even with public notice and comment, Defendants cannot create an implementing regulation that is contrary to the enacting statute. For this reason, this Court concludes that the Defendants’ regulation allowing for the use of trainees as actual surveyors is contrary to the statute.

Having found the regulation invalid, this Court must determine what remedy, if any, is appropriate. NMCC asked the Court to “declar[e] that all deficiencies cited in the SOD and the Final Order that were based on the participation, observations, notes, and/or testimony of trainees are invalid and void.” *See Plf. Sum. Jud. Br. at 39*, ¶ 5. However, this Court has already recommended affirmance of the imposition of DPNA remedy because the deficiencies relied on by the ALJ were made by certified surveyors. Further, this Court has found that NMCC does not have a due process right to have all remaining nine unresolved deficiency citations adjudicated. Given these rulings, this Court must conclude that awarding NMCC the relief it requests would have no effect. For the foregoing reason, NMCC’s Motion for Summary Judgment on the trainee issue should be denied.

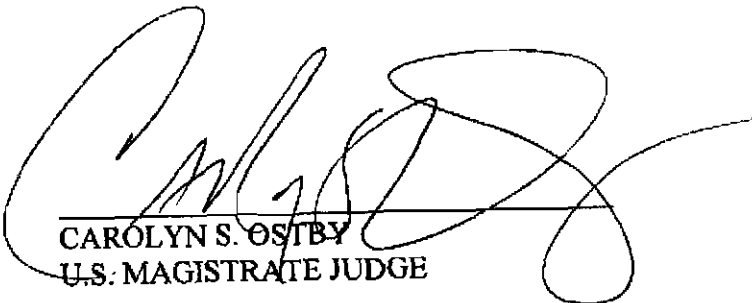
V. CONCLUSION

For the foregoing reasons, IT IS HEREBY ORDERED that Plaintiff’s Motion to Supplement the Record is GRANTED IN PART and DENIED IN PART. The Court also RECOMMENDS as follows:

1. Defendants’ Motion for Summary Judgment (*Doc. # 25*) should be GRANTED.
2. Plaintiff’s Motion for Summary Judgment (*Doc. # 20*) should be DENIED.

The Clerk of Court shall notify the Parties of the making of this Order.

DATED this 30th day of June, 2006.



CAROLYN S. OSTBY
U.S. MAGISTRATE JUDGE